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| EXAMINER SODERQUIST, ARLEN | | | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/598,239

Applicant(s)

VINK ET AL.

Examiner

Arlen Soderquist

Art Unit

1797

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 August 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SI/22)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____
- Paper No(s)/Mail Date ____

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the arrays of sensors in of claims 22-23 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

2. The disclosure is objected to because of the following informalities: page 2, line 33 refers to claims 2-4. Page 3, lines 12 and 17-18 refer to claims 6-10 and 11-22 respectively. These references are improper since the content of the claims may change through cancellation and/or amendment between now and the point that any patent is granted on the instant application. This would change the scope of the disclosure or make the references to the claims meaningless. The references should be removed if they are not required or replaced with the appropriate language from the claims if the information is not found elsewhere in the instant specification.

Appropriate correction is required.

3. Claims 1-4 provide for the use of an organic semiconducting compound to detect NO, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced. For

examination purposes these claims will be treated as claiming the organic semiconducting compound.

4. Claims 1-4 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

5. Claims 10, 16, 20 and 22-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 10 "the FET type element" does not have antecedent basis. In claim 16 "said organic semi-conducting layer" does not have antecedent basis. In claim 20, the reference to claim 9 is improper since claim 9 is not an apparatus claim. For examination purposes examiner will treat this claim as dependent from claim 11. Since claim 22 is dependent from claim 20, the limitation of claim 11 is inherent. What is not clear is if all of the sensors are required to have the form of claim 11.

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-4 and 11-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Bartic (US 6,521,109) or Zhu.

In the patent Bartic teaches a device for detecting an analyte in a sample based on organic materials. The figures and description teach a device having an active layer with at least a dielectric material, a source electrode, a drain electrode and a semiconducting substrate which acts as current pathway between source and drain. The conductivity of said semiconducting layer can be influenced by the interaction of the active layer with the sample containing the analyte to detect. The device is fabricated such that properties like low price, disposability, reduced drift of the device and suitability for biomedical and pharmaceutical applications are obtained. To fulfill these requirements, the device described is based on organic-containing materials. Column 5, lines 45-61 teach that the semiconducting layer is an organic-containing

semiconducting material. The organic-containing semiconducting material can be used in its neutral (undoped) state and can be a p-type semiconductor or an n-type semiconductor but preferably a p-type semiconductor. Said organic-containing semiconducting material can be an organic polymer e.g. a conjugated polymers. Said conjugated polymer can be but is not limited to Polythiophene (PT), poly(p-phenylene) (PPP), poly(p-phenylene vinylene) (PPV), poly(2,5-thiophene vinylene) (PTV), polypyrrole (PPy) or C₆₀ -buckminster fullerene. The organic-containing semiconducting layer can also be a conducting oligomer layer wherein said oligomer layer can be but is not limited to α -hexylthiophene (α -6T), pentacene and oligo-phenylene vinylene.

In the paper Zhu teaches a thin film transistor sensor of the structure shown in figure 1 having the semiconductor pentacene, a source electrode, a drain electrode and a substrate. The structure is anticipatory of the claims even though the intended purpose of NO measurement is not taught by the paper.

8. Claims 1-3, 5, 7-8, 10-11 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Yoshino. In the paper Yoshino examines the electrical conductivity of polythiophene as it contacts various concentrations of nitric oxide. The last paragraph of page 104 teaches that polythiophene is stable and may be suitable for the production of gas sensors.

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. Claims 4, 6, 9, 12, and 14-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yoshino as applied to claims 1-3, 5, 7-8, 10-11 and 13 above, and further in view of Bartic as explained above, Alving (US 5,922,610) and Thomas (US 6,852,996). Yoshino does not teach the scope of organic semiconducting materials, a FET sensor structure, a setup to measure NO in exhaled breath or a sensor array.

In the patent Alving teaches a system to be used for the determination of NO levels in exhaled air and diagnostic methods for disorders related to abnormal no levels. The system is shown in figures 1a and 1b and includes: (i) a face mask that tightly covers the nose and/or mouth of the individual that the mask is intended to be used on; (ii) an inlet unit for inhaled breathing air, (iii) an outlet unit for exhaled breathing air, (iv) a non-rebreathing valve through which inhaled and exhaled breathing air, respectively, passes, and (v) a measuring unit for NO connected to the outlet unit.

In the patent Thomas teaches an organic semiconductor sensor device using pentacene (see column 3, lines 56-60). Sensor cells are arranged in an array in an organic semiconductor layer. Row and column select circuitry addresses the cells of the array one cell at a time to determine the presence of an object, such as a fingerprint ridge or valley, contacting or proximate to a sensing surface above each cell. Control circuitry can be provided in a companion silicon chip or in a second layer of organic semiconductor material to communicate with the array and an associated system processor. The array of sensor cells can be fabricated using a flexible polymer substrate that is peeled off and disposed of after contacts have been patterned on the organic semiconductor layer. The organic semiconductor layer can be used with a superimposed reactive interface layer to detect specific chemical substances in a test medium.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use a FET type of structure as taught by Bartic or Thomas as the sensor type in the Yoshino method and device because of its known use with organic semiconductors to measure components of a medium as clearly shown by Bartic and Thomas. It further would have been obvious to one of ordinary skill in the art at the time the invention was made to use a sensor array as taught by Thomas in the Yoshino device because of the ability to detect a specific chemical substance in a test medium as taught by Thomas. It would have also been obvious to one of ordinary skill in the art at the time the invention was made to place the sensors in an apparatus

for measuring NO in exhaled air as taught by Alving because of the need to measure NO in exhaled air and make determinations about various disease states as taught by Alving.

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The additionally cited art teaches various forms of FET devices or means to measure the NO concentration.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arlen Soderquist whose telephone number is (571)272-1265. The examiner can normally be reached on Monday-Thursday and Alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vickie Kim can be reached on (571) 272-0579. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Arlen Soderquist/
Primary Examiner, Art Unit 1797